EXHIBIT 7

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ABBOTT LABORATORIES

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

IN RE ABBOTT LABS NORVIR ANTITRUST LITIGATION	**Case No. C-04-1511 CW** **NOTICE OF MOTION AND MOTION OF ABBOTT LABORATORIES FOR SUMMARY JUDGMENT** **Date: April 24, 2008** **Time: 2:00 p.m.** **Courtroom 2** **The Honorable Judge Wilken**

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TABLE OF CONTENTS

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TABLE OF AUTHORITIES

Page(s)

CASES

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OTHER AUTHORITIES

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TO PLAINTIFFS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT on April 24, 2008 at 2:00 p.m., or as soon thereafter as the matter may be heard in Courtroom 2, before the Honorable Claudia Wilken, in the United States District Court for the Northern District of California, Oakland Division, defendant Abbott Laboratories will move for summary judgment on Plaintiffs' first claim for relief for monopolization and attempted monopolization under the Sherman Act, their second claim for relief for violation of Cal. Prof. & Bus. Code § 17200, and their third claim for relief for unjust enrichment. Abbott's motion is based on the fact that no genuine issue of material fact is in dispute that would preclude summary judgment, and, therefore, Plaintiffs' three claims for relief cannot stand. Abbott moves pursuant to Federal Rule of Civil Procedure 56 and Local Rule 56.

INTRODUCTION

Discovery has confirmed this is not a proper antitrust case. Based on a monopoly leveraging theory, Plaintiffs contend that Abbott Laboratories raised Norvir's price in December 2003 to thwart competition in the alleged "Boosted Market." But, in fact, competitors' sales have *tripled* since then. Plaintiffs also contend that Norvir's price increase "forced" patients to buy Abbott's combination HIV drug (Kaletra) instead of using Norvir in combination with a competitor's protease inhibitor ("PI"). But after four years of litigation, Plaintiffs have failed to identify a *single patient* who switched to Kaletra because of Norvir's price increase.

Plaintiffs cannot disguise the absence of any legitimate antitrust claim by calling Norvir's new price "unfair" and "outrageous." Regardless of whether they agree with Abbott's pricing decision, Plaintiffs do not dispute that Norvir has "enormous" clinical value for HIV patients. Nor do they dispute that Norvir remains among the lowest-cost HIV drugs despite its enormous value – still sold for $8.57 in a market crowded with $20 and $30 drugs. And they also never dispute that Norvir often pays for itself by reducing the dosage and, thus, the cost of a competitor's PI.

Ultimately, the claims in this case fail as a matter of law in light of the undisputed facts. Although Plaintiffs' claims suffer from many legal deficiencies, this motion focuses on only the most glaring. Each one, by itself, is sufficient to end this case.

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As Abbott explained in its recently filed motion to dismiss a series of related cases, the Ninth Circuit has now rejected Plaintiffs' antitrust theory in *Cascade Health Solutions v. PeaceHealth*, 502 F.3d 895 (9th Cir. 2007) *superseded and amended by Cascade Health Solutions v. PeaceHealth*, No. 05-35627, 2008 U.S. App. LEXIS 2256 (9th Cir. Feb. 1, 2008). In *Cascade*, which post-dates all of this Court's prior substantive rulings in this litigation, the Ninth Circuit held that a monopoly leveraging claim fails as a matter of law unless the plaintiff shows that the defendant priced its bundled product (here, Kaletra) below cost. Rejecting the Third Circuit's holding in *LePage's Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003) (en banc), the Ninth Circuit broadly ruled that "above-cost pricing will not be considered exclusionary conduct for antitrust purposes." *Cascade*, 502 F.3d at 912.

Plaintiffs here have never claimed that Abbott has priced Kaletra below cost. Plaintiffs' expert, Prof. Greer, likewise admits that Abbott has not priced Kaletra below cost. (Hurst Decl., Ex. I at ¶ 35). Plaintiffs' claims, thus, fail as a matter of law solely based on *Cascade* – without regard to any other issue, such as antitrust injury, monopoly power, or patent protection. But the claims fail for additional, independent reasons as well.

First, Plaintiffs have no evidence of antitrust injury as required by the Sherman Act. Antitrust injury is an injury flowing from that which makes the defendant's conduct illegal. *Rebel Oil Co., Inc. v. Atlantic Richfield Co.*, 51 F.3d 1421 (9th Cir. 1995). Here, while the Norvir price increase is the headline of Plaintiffs' complaint, Abbott's conduct is allegedly illegal only because the Kaletra "bundle" is purportedly priced too low compared to the combined price of Norvir and a competitor's PI. But Plaintiffs do not use Kaletra. Their *only* purported injury is paying what they believe is too much for Norvir. That is not an antitrust injury. It is uncontroverted that Abbott has valid patents on Norvir. And the Ninth Circuit has held that a patentee "is entitled to monopoly profits on its patented" products – meaning "any nondiscriminatory price that the market will bear." *Image Technical Services, Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1225-26 (9th Cir. 1997).

Plaintiffs' expert admitted in his deposition that, other than this purported overcharge on Norvir, he "was not able to identify any damage suffered by the plaintiffs." (Hurst Decl., Ex. J, at 198:13-20). When previously denying summary judgment, this Court noted Plaintiffs' reliance on

their "expert's finding that Defendant's price increase harms HIV patients by creating another barrier to entry that hinders the introduction of new PI's from Defendant's competitors." (7/6/06 Order at 12, Docket No. 256). Since then, however, Plaintiffs' expert has conceded that he never even "pretend[ed] to offer any such proof." (Hurst Decl., Ex. I at ¶ 103). On the contrary, he admits that developing new PIs remains a "profitable business," that he has no evidence that PI development "actually f[e]ll due to the price increase," and that he cannot identify how any such issue "impacted, if at all, the plaintiffs in this case." (*Id.*; Hurst Decl., Ex. J at 201:9-15). Without evidence of antitrust injury, Plaintiffs have no antitrust claim.

Second, Plaintiffs have failed to show that Abbott has "monopoly power" in the Boosted Market—another fatal flaw in their Sherman Act claim. This Court previously held that there is factual dispute over Abbott's market share. (9/12/06 Order at 3, Docket No. 146). Discovery has shown, however, that Plaintiffs' sole evidence of monopoly power is a market share calculation that *double- and even triple-counts* Abbott's prescriptions while *single-counting* competitor's prescriptions. Plaintiffs' expert admits that without his improper duplicative counting, he has no opinion on whether Abbott has monopoly power in the Boosted Market. (Hurst Decl., Ex. J at 133:21-134:6). Without evidence of monopoly power, Plaintiffs' claims cannot survive summary judgment.

Third, Abbott's patents warrant summary judgment. A party cannot be liable for unlawfully monopolizing a market that a government-issued patent gives it the legal right to monopolize. Thus, as this Court has noted, antitrust violations are possible only when a patent owner "extends its monopoly *beyond* the scope of the patent." (10/21/04 Order at 4, Docket No. 63 (emphasis added)). That is not the case here. Plaintiffs' expert admits, based on the plain language of the claims, that Abbott's patents in the alleged Boosted Market "accurately capture what's happening out in the marketplace in that alleged market." (Hurst Decl., Ex. N at 60:12-24, 61:1-4).

Plaintiffs seek to avoid this case-ending problem in a variety of ways, none of which has any merit. For instance, Plaintiffs argue that Abbott's patent claims for the use of Norvir as a PI-booster are invalid based on "inherent anticipation." Even if patent validity were relevant to an antitrust analysis, this theory fails because proving anticipation of these claims requires proof that a prior art

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treatment was practiced with "the intent to achieve the objective stated" in the claims. *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1330 (Fed. Cir. 2003). Here, as Plaintiffs' expert admits, the prior art discussed using Norvir for a different objective (attacking the protease enzyme) than the objective claimed in Abbott's patents (boosting another PI's effectiveness). In fact, Plaintiffs' expert concedes that "nothing" in the prior art "even hint[ed]" at that claimed objective before Abbott's invention. (Hurst Decl., Ex. N at 45:6-13). Thus, Abbott's patents are valid as a matter of law.

Finally, Plaintiffs' state law claims are legally defective for many reasons, including the fact that Plaintiffs' claims for unjust enrichment and violations of California's Unfair Competition Law are wholly parasitic on the viability of their federal antitrust claim. As this Court has noted, "[I]f the anti-trust claims fail, both of Plaintiffs' State law claims fail as well." (7/6/06 Order at 23, Docket No. 256). Here, because Abbott is entitled to summary judgment on Plaintiffs' Sherman Act claim, their "State law claims fail as well."

FACTS

A. Abbott's Award-Winning Work On Norvir Produced A Booster With "Enormous Utility."

Plaintiffs' experts now acknowledge Abbott's important contributions to the treatment of HIV, including research dating back to the early years of the epidemic. (*See, e.g.*, Hurst Decl., Ex. R, at ¶ 15). Abbott's development of Norvir, in particular, has resulted in numerous prestigious awards, including awards for the most innovative drug of any kind in the mid-1990s (International Prix Galien Award) and awards hailing Abbott's scientists as "heroes" who greatly benefited humankind (Discoverer's Award and recognition as Heroes of Chemistry). (Hurst Decl., Ex. X, at ¶ 45-47).

Plaintiffs' expert, Prof. Greer, further acknowledges that Norvir has "enormous utility" as a low-dose booster for companion protease inhibitors, which, as the Court knows, are used to combat HIV infections. (Hurst Decl., Ex. J, at 143:6-8). Greer explains that Norvir has "a very large impact in terms of the curative powers of the other products out there." (*Id*. at 153:18-19). When paired with another PI, Norvir "increases the effective concentration" of the second PI in the patient's blood. (Hurst Decl., Ex. Q, at ¶ 164). Norvir thus "allow[s] the use of a second PI that would

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otherwise be of no value because it was metabolized too quickly or allow[s] the second PI to be used at a much less toxic lower dose or at a more convenient dosing interval." (*Id*.) Prof. Greer states that the "combination of Norvir (acting as a booster) plus other PIs was a remarkable development in AIDS/HIV treatment." (Hurst Decl., Ex. H, at ¶ 26).

B. Before December 2003, Norvir's Price Failed To Reflect Its "Enormous Utility" As A Patented Booster.

Despite what everyone agrees is Norvir's "enormous utility" as a low-dose booster, Norvir's price did not account for that clinical value before December 2003, when Abbott adjusted the price to reflect that value for the very first time.

The FDA originally approved Norvir in March 1996 as a stand-alone protease inhibitor, not as a low-dose booster. (Hurst Decl., Ex. J at 134:9-16). As a stand-alone drug, Norvir's recommended daily dose is 1,200 milligrams per day. (*Id*. at 134:17-19). It originally was priced for that dose at about $18 per day, which was typical at the time for the cost of HIV drugs. (*Id*. at 134:20-25, 135:3-10).

It is undisputed that Norvir's original stand-alone price did not account for its tremendous value as a low-dose booster. When Norvir was originally launched, Prof. Greer agrees that Abbott was "thinking of [Norvir] being a stand-alone protease inhibitor" and "[t]hat's how they priced it." (*Id*. at 135:3-10).

Norvir's transformation from a stand-alone drug to a booster accelerated in July 2003 – only months before the price increase – when the FDA gave Bristol Meyers-Squibb (BMS) permission (subject to a license from Abbott) to promote Norvir as a single-pill, 100 mg booster for its own PI, Reyataz. (*Id*. at 143:9-16). Within months of Reyataz's launch, Norvir's most common dose dropped all the way down to 100 mg per day, at a cost of $1.71 based upon the pricing of Norvir as a stand-alone drug. (Hurst Decl., Ex. G at ¶ 155).

That price – $1.71 – was never intended as the price for Norvir as a low-dose booster. $1.71 is arbitrarily one-twelfth the cost of Norvir's stand-alone daily price. That price has nothing to do with Norvir's value as a booster. Prof. Greer concedes that there is no comparison between the value of 100 mg of Norvir as a booster and the value of 100 mg of Norvir as a stand-alone drug: The

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former has "enormous utility" while the latter has almost no value. (Hurst Decl., Ex. J at 137:20-24; Ex. I at ¶ 28).

C. It Is Uncontroverted That Norvir's "Enormous Utility" As A Patented Booster Justifies A "Very Profitable Price."

Notwithstanding its undisputed "enormous" value, Plaintiffs never dispute that Norvir remains among the lowest cost components of an HIV regimen – $8.57 per day in a market crowded with $20 and $30 drugs. (Devlin 1/9/06 Decl. ¶ 12, Docket No. 168). Nor can they contest that Norvir, at $8.57 per day, often pays for itself by reducing the dosage and, thus, the cost of the companion PI. For instance, Lexiva currently costs $40.80 per day at its unboosted dose of four 700-mg tablets. (Hurst Decl., Ex. G at ¶¶ 147, 153; Hurst Decl., Ex. V at NOR 00428746; Hurst Decl., Ex. D at Fletcher 243). 100 mg of Norvir cuts that dose in half to two 700-mg tablets per day. (*Id.*). Taking the lower dose of Lexiva in combination with 100 mg of Norvir per day costs only $28.97, resulting in a net savings of $11.83 per day. (*Id.*).

Moreover, Prof. Greer – who claims to have pricing expertise – acknowledges that Norvir's tremendous boosting value justifies a "very high" price. (Hurst Decl., Ex. J at 152:15-21, 153:21-25, 154:1). Although he did not identify a specific price, he explained that a "very high" or "very profitable price" would be appropriate if Norvir were launched as a 100 mg booster because "it has a very large impact in terms of the curative powers of the other products out there" and, thus, "is a very valuable monopoly." (*Id.* at 153:6-25, 154:1). He personally would have set a "monopoly price" for Norvir to "maximize his profit." (*Id.*).

D. Plaintiffs Concede That Abbott Has Not Engaged In Below-Cost Pricing.

Kaletra is a single tablet with both Norvir's active ingredient (ritonavir) and a companion PI (lopinavir). (7/6/06 Order at 2, Docket No. 256). Plaintiffs claim that by increasing Norvir's price while maintaining Kaletra's price, Abbott made Kaletra a "bargain" compared to the combined price of Norvir and a competitor's PI. (Hurst Decl., Ex. H at ¶ 155). They argue that the reduced difference between Kaletra's price and Norvir's price "forced" consumers to buy Kaletra rather than the comparatively higher-priced combination of Norvir and another PI (almost all of which, incidentally, cost more than Kaletra even before December 2003).

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It is undisputed, however, that Abbott never priced Kaletra below cost. After extensive work on the case, Prof. Greer stated: "I do not accuse Abbott of predatory [below cost] pricing." (Hurst Decl., Ex. I at ¶¶ 27, 35). Kaletra was priced at $18.76 per day in December 2003. Using the Norvir price of $8.57 per 100 mg, and multiplying that by two to account for the 200 mg in a daily Kaletra regimen, Prof. Greer calculated the "implicit price" of the PI component of Kaletra (lopinavir) to be $1.62. (Hurst Decl., Ex. H at ¶ 151). Prof. Greer called $1.62 a "very low" price but not a "below cost" price. (Hurst Decl., Ex. J at 66:17-24).

As Prof. Greer explained, the antitrust theory behind below-cost pricing is that equally-efficient competitors (that is, competitors who can produce their products for the same cost) are forced out of the market because they cannot sell their product at a profit. (Hurst Decl., Ex. J at 59:15-21). If that were true here, of course, Abbott's PI competitors would have reduced their prices to the bare minimum to attempt to stay in the market. But the opposite occurred: Abbott's competitors raised their prices in amounts comparable to Abbott's increase of $6.86 in Norvir's price in December 2003. Since that time, GlaxoSmithKline (GSK) has raised the wholesale list price of Lexiva by nearly $9 ($32.00 to $40.80) and BMS has increased the wholesale list price of Reyataz by $5.34 ($22.08 to $27.42). (*E.g.*, Hurst Decl., Ex. G at ¶ 147).

Plaintiffs contend that Kaletra's "bargain" price has "forced" patients to buy Kaletra rather than the relatively more expensive combination of Norvir plus a competitor's PI. But Plaintiffs have been unable to identify even one patient who switched to Kaletra for that reason. (Hurst Decl., Ex. N at 80:21-24, 81:1-19, 293:2-18). Plaintiffs' expert HIV practitioner, Dr. Volberding, admits that the pricing comparison did not impact his prescription practices. (*Id*. at 296:12-18). Abbott's expert HIV practitioner, Dr. Scott, testified the same way and likewise is not aware of even one patient's switching to Kaletra for this reason. (Hurst Decl., Ex. P at ¶¶ 45-56).

None of this is surprising. Price does not drive prescribing decisions because virtually no one who makes those decisions, HIV practitioners and patients, actually pays for Norvir. (Hurst Decl., Ex. N at 79:16-24, 80:1-10). Private insurers pay. And Abbott took steps to ensure that the price remained the same for all government programs and also expanded its public access program to make it simple and easy for uninsured patients to get the drug free. (Hurst Decl., Ex. G at ¶ 79

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n.242).

Far from the price increase suppressing sales, Norvir's use as a booster has skyrocketed since December 2003. The prescription volume for Norvir has tripled, going from 20,000 prescriptions in November 2003 to 63,805 prescriptions in September 2007. (Hurst Decl., Ex. J at 161:23-25, 162:1-7; 165:25, 166:1-7). Similarly, the prescription volume of BMS's PI, Reyataz, which is prescribed with Norvir as a booster, has more than tripled, going from 16,250 prescriptions in November 2003 to over 51,000 in November 2007. (*Id*. at 162:18-25, 163:1-4). That is a 320% increase in four years – an increase BMS achieved despite raising its own prices three times during that period. (Hurst Decl., Ex. G at ¶¶ 146-47).

Prof. Greer nevertheless maintains that Kaletra's market share in the alleged "Boosted Market" would be lower today if Kaletra's price were higher in comparison to Norvir. But Prof. Greer cannot say by how much, or even whether the difference would be more than a mere 5%. (Hurst Decl., Ex. J at 180:4-25, 181:1-7). For his claim that Kaletra's market share would be lower by some unspecified amount, Prof. Greer relies primarily on the fact that Kaletra sales exceeded Abbott's internal *forecasts* generated before Norvir's price increase (Hurst Decl., Ex. H at ¶¶ 178-79) – an argument Prof. Greer makes despite volunteering at his deposition that economists have an "old joke" that "clearly it's difficult to forecast, especially about the future." (Hurst Decl., Ex. J at 193:9-11).

E. Plaintiffs' Expert Artificially Hikes Up Abbott's Market Shares By Double- And Triple- Counting Abbott's Prescriptions.

Plaintiffs' amended complaint defines the monopolized "Boosted Market" as "the market for PIs only when prescribed together with Norvir as a booster." (Doe Plaintiffs' Am. Compl. ¶ 27, Docket No. 38; *accord* 9/12/05 Order at 2, Docket No. 146 (stating that the "amended complaint defines [the market] as the market for those PIs that are prescribed for use with Norvir as a booster"); 7/06/06 Order, Docket No. 256 ("[P]laintiffs define [relevant market] as the market for those PIs, such as Reyataz, Lexiva and Kaletra, that are prescribed for use with Norvir as a booster.")).

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Abbott disagrees with these market definitions. Under proper market definitions that account for all directly competing products, Abbott has only 15.3% of the relevant prescription market. (*See* Hurst Decl., Ex. G at ¶¶ 57, 66, 67, 70, 72, 100). Nevertheless, solely for the purposes of this motion, Abbott is not challenging Plaintiffs' more narrow market definitions.

Even under those definitions, however, straightforward math – that is, comparing the number of Kaletra prescriptions to the number of prescriptions of other boosted PIs – establishes that Abbott's share of the alleged "Boosted Market" dropped rapidly from 73.8% in 2003 to 45.4% in 2007. (*Id*. at ¶ 138). Prof. Greer does not dispute that measuring market share in this straightforward way leads to the conclusion that Abbott lacks market power. (Hurst Decl., Ex. J at 133:21-25).

Instead, Prof. Greer calculates Abbott's market share in a convoluted and facially illegitimate manner. In fact, he double- and even triple-counts Abbott's prescriptions while single-counting competitors' prescriptions. For the purportedly-leveraged "Booster Market" – which Prof. Greer defines as a one-product market consisting solely of ritonavir (Norvir's active ingredient) – Prof. Greer counted each prescription of Norvir as one prescription and also counted the ritonavir component of Kaletra as one prescription. (*Id*. at 69:16-24; *accord* Hurst Decl., Ex. G at ¶¶ 132, 136-37).

But Prof. Greer then counts all of those *booster* prescriptions again in the purportedly "separate" *Boosted* Market. To explain why he double-counted Norvir prescriptions, Prof. Greer stated that the drug is "in both markets" at the same time. (Hurst Decl., Ex. J at 70:3-7). Using the same rational, Prof. Greer triple-counted each Kaletra prescription. He counted the ritonavir component as two prescriptions, one for the Boosted Market and one for the Booster Market, and he then counted the lopinavir component as another prescription in the Boosted Market. (*Id*. at 86:13-20).

This duplicative counting inflates Abbott's market share in the Boosted Market. For example, under straightforward math, Abbott had only 571,000 prescriptions in 2003 for Kaletra and, thus, had only 571,000 boosted PI (lopinavir) prescriptions in the Boosted Market. (Hurst Decl., Ex. J at 69:22-24). Prof. Greer's method, however, credited Abbott with 1,342,000

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prescriptions in the Boosted Market – a 135% increase – which he managed by, first, doubling the Kaletra prescriptions from 571,000 to 1,142,000 and then adding another 200,000 prescriptions based on prescriptions written for Norvir as a booster for other PIs . (*Id*. at 70:15-17, 79:5-25, 80:1-16).

It is only through these manipulations that Prof. Greer concludes that Abbott's share of the Boosted Market started at 83.1% in December 2003 and fell to only 73.9% in December 2005. (Hurst Decl., Ex. H at ¶ 111).

F. It is Uncontroverted That Plaintiffs Have Not Suffered Antitrust Injury.

The class in this litigation is defined as those who paid for, or reimbursed another who paid for, Norvir as a booster to other protease inhibitors. (6/11/07 Order at 21, Docket No. 345). The complaint alleges that the class's "injury consists of being forced to pay higher prices for Norvir." (Doe Am. Compl. ¶ 46, Docket No. 38). Of course, what allegedly violates the Sherman Act here is not Norvir's price. Instead, it is the purported resulting "bargain" price for Kaletra that allegedly forced patients to switch to Kaletra.

As shown further below, therefore, paying an allegedly high price for Norvir is not an antitrust injury. Nevertheless, this is the only purported injury that Plaintiffs and their expert have identified in this litigation:

> Q. So, therefore, in terms of coming up with an opinion on damages in this case, you were not able to identify any damage suffered by the plaintiffs in this case besides paying more for the Norvir price increase?
>
> A. I wasn't able to, no, to estimate anything else apart from the higher price for the Norvir.

(Hurst Decl., Ex. J at 198:12-20).

Prof. Greer does argue that Kaletra's market share would have been lower absent the price increase. But he has offered no opinion about how any such alleged market share reduction "harmed, if at all, any of the plaintiffs in this case." (*Id*. 200:18). In fact, Prof. Greer believes that any market share reduction would impact only patients "on Kaletra" who "would not otherwise have been on Kaletra." (*Id*. at 200:15-24). Of course, that does not include the class plaintiffs, who are

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by definition Norvir purchasers, and it does not include the class representative, Doe 1, who has never even taken Kaletra. (6/11/07 Order at 21, Docket No. 345).

In connection with Abbott's earlier motion for summary judgment on antitrust injury, Plaintiffs avoided summary judgment by relying on an affidavit from Prof. Greer implying that Norvir's price increase may have harmed Plaintiffs by reducing the incentive to develop PIs. (7/6/06 Order at 12, Docket No. 256). In subsequent discovery, however, Prof. Greer admited that he "cannot really prove [that claim] one way or the other." (Hurst Decl., Ex. J at 195:25, 196:1). Indeed, two new PIs have launched since the price increase (Prezista and Aptivus), and several more are on their way. (Hurst Decl., Ex. G at ¶¶ 60, 107, 148). Additionally, Prof. Greer admits that he has no evidence that Plaintiffs themselves were impacted by any purported reduced incentive to develop new PIs:

> Q. But you have not been able to identify how this innovation effect from Abbott's allegedly anticompetitive conduct impacted, if at all, the plaintiffs in this case; correct?
>
> A. That's correct.

(Hurst Decl., Ex. J at 201:9-15).

G. The United States Patent And Trademark Office Awarded Abbott Multiple Patents On Norvir And Its Use As A Booster To PIs.

With respect to the patent issues, it is undisputed that Abbott was properly awarded a patent on ritonavir (Norvir's active ingredient) – U.S. Patent No. 5,541,206. Thus, it is uncontroverted that Abbott has legitimate monopoly power over all sales of Norvir. (10/21/04 Order at 5, Docket No. 63; 3/2/05 Order at 2-3, Docket No. 44; Hurst Decl., Ex. X at ¶¶ 210-13).

Abbott also was awarded two patents on Norvir's use as a booster to other PIs – U.S. Patent Nos. 6,703,403 and 6,037,157. For example, dependent claim 22 of the '403 patent is directed to "improving the pharmacokinetics" of an "HIV protease inhibitor" by administering Norvir (i.e., ritonavir) to a "human in need of such treatment":

> 21. A method for improving the pharmacokinetics of a drug which is metabolized by cytochrome P450 monooxygenase comprising administering to a human in

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need of such treatment an amount effective to inhibit cytochrome P450 monooxygenase of ritonavir or a pharmaceutically acceptable salt thereof.

22. The method of claim 21 wherein the drug which is metabolized by cytochrome P450 monooxygenase is an HIV protease inhibitor.

(Hurst Decl., Ex. K at Claims 21 and 22).

Abbott has identified 36 claims that similarly cover the "combination of ritonavir (Norvir) and other PIs," which Plaintiffs have defined as the "Boosted Market." (Hurst Decl., Ex. H at ¶¶ 89, 96). Abbott offered the expert report of a renowned HIV clinician, Dr. Courtney Fletcher, to provide the technical background demonstrating that the plain language of all these claims covers the Boosted Market. (Hurst Decl., Ex. O at ¶¶ 20-50).

Plaintiffs' expert, Dr. Volberding, agrees. Though he testified that he lacked the expertise to construe the claims, Dr. Volberding studied the booster patents for his validity opinions. (Hurst Decl., Ex. Q at ¶ 13). After having done so, he testified, for instance, that claim 21 of the '403 patent "accurately captures what's happening out in the marketplace when ritonavir is prescribed to boost companion protease inhibitors." (Hurst Decl., Ex. N at 61:23-62:19). He similarly conceded that "the statement in Claim 1 [of the '403 patent] is what's happening in the world." (*Id*. at 61:2-4).

Abbott's competitors similarly have recognized that the '403 and '157 patents cover the so-called Boosted Market. At considerable expense, Abbott's four major competitors in the Boosted Market have taken a license to these patents for the express purpose of "promot[ing] and market[ing] certain of [their] products with Ritonavir for the purpose of co-prescription/co-administration." (Hurst Decl., Ex. F at 1; *see also* Exs. A at 1; B at 1; C at 1; E at 1.[1] These four manufacturers – GSK, BMS, Boehringer Ingelheim International (BI), and Tibotec Pharmaceuticals Limited – accounted for five out of the seven competing boostable PIs (Reyataz, Lexiva, Agenerase, Prezista and Aptivus). *Id.* Those competitors accounted for about 89% of competing PI sales in September 2007.[2]

[1] A fifth competitor, Pfizer, has taken a license for a non-PI HIV drug.

[2] The total prescriptions for non-Abbott boostable PIs during September 2007 were Reyataz (BMS, 51,919), Lexiva (GSK, 15,662), Prezista (Tibotec, 7,322), Crixivan (Merck, 3,471), Aptivus (BI, 1,612), Agenerase (GSK, 30), and Invirase (Hoffmann-La Roche, 5,623). (Hurst Decl., Ex. U at

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H. Contrary To Plaintiffs' Invalidity Theory, Plaintiffs' Expert Now Admits That The Prior Art Did Not Even "Hint" At Norvir's Boosting Properties.

Plaintiffs argue that Abbott's booster patents are invalid as anticipated (*i.e.*, not "new" on the filing date of June 29, 1995 of the relevant patent application). Abbott believes that patent validity is not relevant to an antitrust analysis. Regardless, the uncontroverted facts show that Abbott's patents are valid.

There is no dispute that Norvir was the first drug ever approved as a booster for any drug based on an ability to inhibit the PI-eating enzyme called "cytochrome P450." (Hurst Decl., Ex. X at ¶ 138). By blocking that enzyme, Norvir boosts the blood levels of the companion PI. (*Id*. at ¶ 87). To this day, Norvir "remains the only drug in FDA history to be approved as a booster based on an inhibitory effect" on that enzyme. (*Id*. at ¶ 138; *see also* Hurst Decl., Ex. N at 229:6-22; 228:13-14 (acknowledging Norvir's unique property as the "most potent" known cytochrome P450 inhibitor)).

Dr. Volberding now concedes that nothing in the prior art "hinted" at Abbott's claimed boosting method of treating HIV. (Hurst Decl., Ex. N at 39:21-24, 40:1-6). Dr. Volberding likewise agrees that no one knew before June 29, 1995 that Norvir had the ability to inhibit cytochrome P450:

> Q. Turning back to the time period again, June 29, 1995, are you aware of anything in the scientific literature, any prior art at all, even suggesting or hinting at the possibility that ritonavir [Norvir] could act as an inhibitor of cytochrome P450?
>
> A. I don't recall seeing any reference to that action of ritonavir before that date.

(*Id*.).

Because nobody knew that Norvir inhibited cytochrome P450, the scientific literature before June 1995 also did not suggest that Norvir could boost other PIs. Dr. Volberding admitted that point, too:

> Q. You agree that before June 29, 1995, nothing in the scientific literature and nothing in the prior art discloses any instance even hinting that ritonavir was to be given with the express intent of improving the pharmacokinetics of a

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companion PI?

A. I think that's true.

(*Id*. at 45:5-13).

At the conclusion of discovery, it remains undisputed that the prior art did not disclose using Norvir to boost the blood levels of a PI by inhibiting cytochrome P450. (Hurst Decl., Ex. X at ¶ 102). The prior art disclosed only using Norvir for a different purpose – namely, to inhibit a different enzyme, HIV's protease enzyme, which helps HIV replicate. (*Id*. at ¶ 101). When using Norvir for that purpose, even when combined with other PIs, Norvir's role is to slow HIV replication by helping inhibit the protease enzyme. That is entirely different from the claimed invention.

ARGUMENT

"Summary judgment is proper where no genuine issues of material fact remain in dispute, such that the moving party is entitled to judgment as a matter of law." *Jespersen v. Harrah's Operating Co., Inc.*, 392 F.3d 1076, 1079 (9th Cir. 2004). "A mere scintilla of evidence supporting the non-moving party's position is insufficient; there must be evidence on which a jury could reasonably find for the non-moving party." *Rivera v. Philip Morris, Inc.*, 395 F.3d 1142, 1146 (9th Cir. 2005). Here, Abbott is entitled to summary judgment on multiple independent grounds.

I. *Cascade* Mandates Entry Of Summary Judgment In Abbott's Favor.

"[T]o demonstrate attempted monopolization a plaintiff must prove . . . that the defendant has engaged in predatory or anticompetitive conduct. . . ." *Cascade Health Solutions v. PeaceHealth*, 502 F.3d 895, 904 (9th Cir. 2007); *Image Technical Servs. v. Eastman Kodak Co.*, 125 F.3d 1195, 1202 (9th Cir. 1997). Here Plaintiffs' only theory of predatory or anticompetitive conduct is monopoly leveraging based upon Abbott's decision to increase Norvir's price without increasing Kaletra's price. They argue that, with the current stand-alone price of Norvir, Abbott is heavily discounting its PI in the Kaletra bundle and thereby forcing patients to chose Kaletra over competitors' PIs. As Plaintiffs allege in their amended complaint, Abbott is purportedly "pricing others out of the market" for boosted PIs – that is, Abbott is purportedly pricing the boosted PI component of Kaletra so low that others' PIs cannot profitably compete. (Doe. Am. Compl. ¶ 21, Docket No. 38).

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Since this Court's prior decisions, the Ninth Circuit has issued an exhaustive, 35-page opinion regarding monopoly leveraging and, in particular, when bundled pricing is so low that it can create liability under Section 2 of the Sherman Act. *Cascade Health Solutions v. PeaceHealth*, 502 F.3d 895 (9th Cir. 2007). The defendants in *Cascade* were a group of local hospitals named PeaceHealth that had a 90 percent market share in tertiary care – that is, the provision of complex services like cardiovascular surgery – and also had a 75 percent market share of primary and secondary care – that is, more common medical services like setting a broken bone and performing a tonsillectomy. The plaintiff was a small local hospital named McKenzie that provided only primary and secondary care. PeaceHealth offered insurers lower "bundled" pricing if they made PeaceHealth their sole preferred provider for all services – primary, secondary and tertiary. McKenzie claimed that the lower bundle pricing constituted attempted and actual monopolization under Section 2 of the Sherman Act. The Ninth Circuit framed the issue as follows:

> How are we to discern where antitrust law draws the line between bundled discounts that are procompetitive and part of the normal rough-and-tumble of our competitive economy and bundled discounts, offered by firms holding or on the verge of gaining monopoly power in the relevant market, that harm competition and are thus proscribed by § 2 of the Sherman Act?

Id. at 907.

To answer this question, the Ninth Circuit first considered the Third Circuit's opinion in *LePage's Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003), which the Plaintiffs have repeatedly relied on in this litigation. (Hurst Decl., Ex. H. at ¶¶ 131-132; Hurst Decl., Ex. I. at ¶¶ 5, 34 ("I reviewed the *LePage's v. 3M* case, which illustrates this perfectly.")). In *LePage's*, the Third Circuit held that the question of whether bundle discounting was exclusionary was to be decided based upon whether there was a legitimate business reason for the discounting. Under *LePage's*, antitrust liability could be imposed without "consider[ation] of whether the defendant priced below cost." 502 F.3d at 909.

The Ninth Circuit expressly rejected that holding, based primarily on the fact that "the Supreme Court "has forcefully suggested that we should not condemn prices that are above some measure of incremental cost." *Cascade*, 502 F.3d a 911. The Ninth Circuit found that the Supreme

Court has given "broad application of the principal that only below-cost prices are anticompetitive." *Id.* Any other pricing either "represents competition on the merits, or is beyond the practical ability of a judicial tribunal to control without courting intolerable risks of chilling legitimate price-cutting." *Id.* On this basis, the Ninth Circuit declined to follow *LePage's* and held instead that "the exclusionary conduct element of a claim arising under § 2 of the Sherman Act cannot be satisfied by reference to bundled discounts unless the discounts result in prices that are below an appropriate measure of the defendant's costs." *Id.* at 914.

The Ninth Circuit went further and specifically "define[d] the appropriate measure of the defendant's costs in bundled discounting cases and how we determine whether discounted prices fall below that mark." *Id.* The Court explained:

> Under this standard, the full amount of the discounts given by the defendant on the bundle are allocated to the competitive product or products [here the PI portion of Kaletra]. If the resulting price of the competitive product or products is below the defendant's incremental cost to produce them, the trier of fact may find that the bundled discount is exclusionary for purposes of § 2. *This standard makes the defendant's bundled discounts legal unless the discounts have the potential to exclude a hypothetically equally efficient producer of competitive products.*

Id. at 916 (emphasis added and omitted).

Cascade mandates summary judgment in Abbott's favor. Plaintiffs concede that they "do not accuse Abbott of predatory [below cost] pricing." (Hurst Decl., Ex. I. At ¶ 35). Using the same method *Cascade* mandated for calculating whether below-cost pricing has occurred, Prof. Greer applied the full amount of the Kaletra bundle discount to the PI portion of Kaletra (the "competitive product" in the bundle), and came up with an "implicit" discounted price of $1.62 for Abbott's PI in Kaletra. (Hurst Decl., Ex. H at ¶¶ 142-153). Prof. Greer called this a "very low" price but not a below cost price. (*Id.* ¶¶ 151-52).

This is fatal to plaintiffs' Sherman Act claim. *Cascade* mandates that "a plaintiff who challenges a package discount as anticompetitive *must prove* that, when the full amount of the discounts given by the defendant is allocated to the competitive product or products, the resulting

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price of the competitive product is below the defendant's incremental cost to produce them." 502 F.3d at 919 (emphasis added). Plaintiffs have not done so.

Plaintiffs instead have attempted to distinguish *Cascade* on the bases that: (1) Abbott does not offer its PI (lopinavir) separate from the Kaletra bundle and (2) the immediate cause of the price differential was an increase in Norvir's price rather than a decrease in Kaletra's price. Neither purported distinction is material.

First, the theory of monopoly leveraging is that the monopolist in one market (here the Booster Market) uses its power in that market to force buyers to take its competitive product in another market (here the Boosted Market) by pricing that product too cheaply if purchased with the monopoly product. Whether the monopolist also offers the competitive product (here Abbott's PI, lopinavir) outside of the bundle is completely irrelevant. The relevant point is that Plaintiffs accuse Abbott of selling Norvir more cheaply when it is bundled in Kaletra than when it is sold as a stand-alone product. (Hurst Decl., Ex. H at ¶ 155).

Indeed, Prof. Greer himself describes Kaletra as a "bundled product," (Hurst Decl., Ex. J at 34:19), which he contends Abbott improperly offers at a "bargain" price. (Hurst Decl., Ex. H at ¶ 155). That is bundled discounting. *Cascade* likewise defines bundling as "the practice of offering, for a single price, two or more goods or services that *could* be sold separately" – not that are both actually sold separately. 502 F.3d at 905. *Cascade* also notes "the varied and pervasive nature of bundled discounts" and offers numerous examples without ever suggesting that there is any significance to whether both of the products are actually sold outside of the bundle. *Id.*

Second, Plaintiffs' other purported distinction – that Abbott raised Norvir's price rather than lowering Kaletra's price – is also a distinction without a difference. Monopoly leveraging, as defined by the Ninth Circuit, is "exploiting a dominant position in one market to expand the empire into the next." *Image Tech.*, 125 F.3d at 1216. It is the *result* – that the competitive product in the bundle (here Abbott's PI) is cheaper than the competitors' product (here, other drug companies' boosted PIs) – that allegedly pushes consumers to purchase the bundle. The *method* by which the competitive product becomes cheaper in the bundle is irrelevant. Plaintiffs' amended complaint itself makes the point that it is the *result* that is significant. (Doe. Am. Comp. ¶ 21, Docket No. 38

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("*As a result* [of Abbott's failure to raise the price of Kaletra], Kaletra became the least expensive boosted regimen in the Boosted Market") (emphasis added)); *see also Williamson Oil Co., Inc. v. Phillip Morris USA*, 346 F.3d 1287, 1307 n.12 (11th Cir. 2003) (noting in Sherman Act Section 1 case that a price gap could have been widened either by increasing some prices or by decreasing others).

The irrelevance of the *cause* of the price differential is clear as well from the fact that Abbott has a valid patent on Norvir. "[S]etting high prices in the original 'monopoly' market" is among the "ways that a monopolist can permissibly benefit from its position" under the patent laws. *Alaska Airlines, Inc. v. United Airlines, Inc.*, 948 F.2d 536, 548-49 (9th Cir. 1991). The Ninth Circuit made the same point in *Image Technical Services v. Eastman Kodak Co.*, 125 F.3d 1195, 1226 (9th Cir. 1997), where the court specifically struck the portion of posttrial injunction requiring "reasonable" prices. That court explained that the defendant "is entitled to monopoly prices on its patented and copyrighted parts" and that any judicial effort to limit those prices is "generally considered beyond [judicial] function, namely, direct price administration." *Id*. at 1225; *accord Verizon Communs., Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (U.S. 2004) ("The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system.").

Plaintiffs' expert made a similar point in his deposition – that it is solely the price differential between stand-alone Norvir and the Kaletra bundle that gives rise to the alleged monopoly leveraging, not the increase in the price of Norvir:

> Q. [I]f in December of 2003 when Abbott raised the price of Norvir, if it had at the same time raised the price of Kaletra a commensurate amount, you would again agree there would be no possible antitrust violation; right?
>
> A. I say that in my report and also in my reply, yes.

(Hurst Decl., Ex. J at 38:22-25, 39:1-7).

Even if Plaintiffs were right that Abbott's conduct somehow did not technically qualify as the type of "bundled discounting" discussed in *Cascade*, Plaintiffs' claim would still fail. Plaintiffs have argued that Abbott's conduct was a "first cousin" to "bundled discounting" and "raising rival's

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costs." (Hurst Decl., Ex. H at ¶ 135). But *Cascade* held that *neither* practice qualifies as exclusionary conduct without below-cost pricing. 502 F.3d at 911. If below-cost pricing is required to show that both "first cousins" are exclusionary, Abbott's pricing decisions *also* require below-cost pricing to be exclusionary. Plaintiffs have offered no reason for holding otherwise.[3]

In short, under *Cascade,* Plaintiffs' allegation that Abbott engaged in exclusionary conduct fails as a matter of law. Summary judgment is appropriate on that basis alone.

II. Plaintiffs' Sherman Act Claim Fails Because Plaintiffs Have Offered No Evidence Of Antitrust Injury In The Boosted Market

Plaintiffs' Sherman Act claim also fails because Plaintiffs have no evidence that they suffered any antitrust injury. As this Court stated in its July 6, 2006 Order, "To show an anti-trust injury, Plaintiffs must prove that their loss flows from an anti-competitive aspect or effect of Defendant's behavior." (*Id.* at 11 (quoting *Rebel Oil Co.*, 51 F.3d at 1433). As the Supreme Court explained, it is not enough for an injury to be "causally related to an antitrust violation." *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990). It must actually be "attributable to an anti-competitive aspect of the practice under scrutiny" and must be "injury of the type the antitrust laws were intended to prevent." *Id.*

In its earlier summary judgment motion, Abbott showed that Plaintiffs failed to establish "antitrust injury" because the only harm they alleged in the amended complaint was paying more for Norvir. This purported harm is not "attributable" to the allegedly "anti-competitive aspect of the practice under scrutiny" – the alleged "bargain" price on Abbott's PI in the Kaletra bundle to attempt to monopolize the market for boosted PIs in the *Boosted* Market. Rather, this purported harm is a by-product of Abbott's perfectly lawful decision to set the price of its *patented* drug in the separate

[3] When responding to Plaintiffs' argument that Abbott's conduct was the "first cousin" to bundled discounting, Abbott's economic expert noted that there is no evidence Abbott actually "offer[s] discounts on Norvir contingent on the patient purchasing lopinavir" and, thus, Abbott has not engaged in bundled discounting. (Hurst Decl., Ex. G at ¶ 8). That is true because, unlike when Norvir was launched as a stand-alone PI in 1996, Kaletra's original price in 2000 was set with full knowledge and intent that ritonavir would be acting as a booster. Thus, there is no basis to assert that Abbott offers any discount for the ritonavir component of Kaletra compared to the boosting price Abbott set for stand-alone Norvir in December 2003. Nevertheless, the fact remains that Plaintiffs' sole theory of exclusionary conduct is that Abbott does offer such discounts, which Abbott's expert noted fails under *Cascade* because "plaintiffs and Prof. Greer do not, and cannot, allege that the implicit price of lopinavir is below cost." (*Id.*).

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Booster market.

To avoid that clear deficiency in their claim, Plaintiffs previously directed the Court to a section of Prof. Greer's declaration that generally referred to Abbott's pricing decisions "diminish[ing] the incentive" of Abbott's competitors to enter the Boosted Market. (2/08/06 Greer Decl. ¶ 61, Docket No. 181). At the time, the Court accepted Plaintiffs' argument, explaining that "Plaintiffs provide their expert's finding that Defendant's price increase harms HIV patients by creating another barrier to entry that hinders the introduction of new PIs from Defendant's competitors, and, therefore, provides evidence of anti-trust injury." (7/6/06 Order at 12, Docket No. 256).

Since then, however, Prof. Greer has admitted that he has no support for this supposition, stating that he never even "*pretend[ed] to offer any such proof.*" (Hurst Decl., Ex. I at ¶ 103 (emphasis added)). This lack of evidence is independently fatal to Plaintiffs' antitrust claim. "A court is not bound by the mere assertions of an expert . . . and must 'look behind the expert's ultimate conclusion . . . and analyze the adequacy of its foundation." *O'Connor v. Commonwealth Edison Co.*, 807 F. Supp. 1376, 1389 (C.D. Cal. 1992). In other words, "[e]xpert testimony is useful as a guide to interpreting market facts, but it is not a substitute for them." *Brooke Group v. Brown & Williamson Tobacco Co.*, 509 U.S. 209, 242 (1993). "When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, . . . it cannot support a jury's verdict." *Id*; *see also Rebel Oil Co.*, 51 F.3d at 1435-36 (same).

Since his preliminary declaration, Prof. Greer has conceded that he knows of no evidence supporting the notion that Norvir's price increase actually impacted the level of innovation in the Boosted Market:

> My remarks on reduced incentives for innovation stemming from the price increase were meant to be unexceptional observations about incentives. ***I do not think it is possible to prove that innovation would actually fall due to the price increase, and I did not pretend to offer any such proof.*** I think the empirical complexities of doing so make that impossible.

(Hurst Decl., Ex. I at ¶ 103 (emphasis added)). Indeed, in his deposition, Prof. Greer went further

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and affirmatively agreed that "despite the Norvir price increase, it is *still a profitable business* to sell and develop boostable protease inhibitors." (Hurst Decl., Ex. J at 197:4-7 (emphasis added)).

Plaintiffs' technical expert, Dr. Volberding, agreed as well. He admits that he is "not aware of any drugs that haven't been developed because of the Norvir price increase" and that HIV drug research programs for drugs boosted by Norvir are "proceeding." (Hurst Decl., Ex. N at 173-75). Abbott's expert agrees too. (Hurst Decl., Ex. O at ¶¶ 83-84; Ex. X at ¶ 237; Ex. G at ¶¶ 148, 150). As noted above, two new boostable PIs have been approved by the FDA since the price increase (Prezista in June 2006 and Aptivus in June 2005) and others are being tested in clinical trials. (Hurst Decl., Ex. G at ¶¶ 107, 148).

Moreover, even if Plaintiffs had any competent evidence that Norvir's price increase impacted the level of innovation in the Boosted Market – which they do not – they have no proof that the purported innovation effect harmed *them*. Prof. Greer admittedly has "not been able to identify how this innovation effect from Abbott's allegedly anticompetitive conduct impacted, if at all, the plaintiffs in this case." (Hurst Decl., Ex. J at 201:9-15). Nor could he. It is impossible to say that a hypothetical new drug that was not actually developed would have benefited Plaintiffs. (*See* Hurst Decl., Ex. G at ¶ 149).

Because Plaintiffs have no evidence that they suffered any antitrust injury, Abbott is entitled to summary judgment on their Sherman Act claim.[4]

[4] At the motion to dismiss stage, this Court held that the Doe plaintiffs had standing to seek injunctive relief under the Sherman Act pursuant to *Blue Shield of Va. v. McCready*, 457 U.S. 465 (1982). *Doe v. Abbott Labs.*, C 04-1511 CW, 2004 U.S. Dist. LEXIS 29129, at *11-12 (N.D. Cal. Oct. 21, 2004). In *McCready*, however, the Plaintiffs alleged that they suffered an injury in the relevant alleged antitrust market directly due to the anticompetitive conduct under scrutiny – namely, an "unlawful conspiracy in violation of § 1 of the Sherman Act." 457 U.S. at 470. Here, by contrast, Plaintiffs allege that they suffered injury in the *Booster* Market due to having to pay more for Norvir, which, again, is the result of Abbott's perfectly lawful decision to raise Norvir's price. Plaintiffs have failed to offer any evidence that they suffered injury in the relevant *Boosted* Market from Abbott's purported "bargain" price for the Kaletra bundle, which they do not even buy. In any event, *McCready* was decided at the dismissal stage. Here, with the benefit of full discovery, it is clear that Plaintiffs were not injured by any "act alleged to be in violation of the antitrust laws." *Glen Holly Entm't, Inc. v. Tektronix Inc.*, 352 F.3d 367, 376 (9th Cir. 2003).

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III. Plaintiffs' Sherman Act Claim Fails Because Plaintiffs Cannot Show That Abbott Has Monopoly Power In The Boosted Market Or A Dangerous Probability Of Acquiring Such Power.

To establish their claim under section 2 of the Sherman Act, Plaintiffs must prove that Abbott has "monopoly power" in the Boosted Market (monopolization) or a dangerous probability of acquiring such power (attempted monopolization). (7/06/06 Order at 6, Docket No. 256). In deciding Abbott's prior summary judgment motion, the Court stated that it was not in a position to resolve the competing views on monopoly power. (*Id*. at 9).

In making that determination, this Court ruled that Plaintiffs are continuing to pursue a two-market theory (as required for monopoly leveraging) rather than a one-market theory (which would obviously end their case). Abbott accepts that ruling and, thus, focused during discovery on precisely how Plaintiffs calculated the relevant market shares for the two alleged markets. That discovery has shown that Plaintiffs' assertion of monopoly power depends solely on facially nonsensical market share calculations.

Specifically, as detailed in pages 8-10 above, Plaintiffs' expert reaches his opinions based on double- and triple-counting Abbott prescriptions while single-counting competitor's prescriptions. He conceded at his deposition that he had not "offered an opinion" using any other method of calculation. (Hurst Decl., Ex. J at 133-34).

This Court need not and should not find a genuine issue of fact from such an unreasonable purported expert opinion. Expert opinions on economic issues should be rejected as a matter of law if "indisputable record facts contradict or otherwise render the opinion unreasonable." *Brooke Group*, 509 U.S. at 242. Whether they are reasonable is judged from the "substantive law which is the foundation for the claim or defense." *Rebel Oil Co.*, 51 F.3d at 1435-37.

Plaintiffs purport to support their expert's nonsensical duplicative counting based upon the assertion – contrary to the operative complaint – that the Booster Market overlaps with the Boosted Market. But the law of monopoly leveraging is clear that there must be two "separate" and "distinct" markets. *Image Technical Servs., Inc.*, 125 F.3d at 1216; *Catlin v. Washington Energy Co.*, 791 F.2d 1343, 1348-49 (9th Cir. 1986). Identifying a "distinct, separate and second market" –

rather than an overlapping market – is a "threshold requirement" essential to proving their claim. *Catlin*, 791 F.2d at 1346, 1349. "[U]nder a monopoly leveraging theory, 'the market identification burden is compounded . . . because proof of the existence of two separate product or service markets is necessary.'" *Id.* Absent "a distinct, separate and second market," a monopoly leveraging claim fails as a matter of law. *See Cost Mgmt. Servs. v. Washington Natural Gas Co.*, 99 F.3d 937, 951 (9th Cir. 1996) ("'monopoly leveraging' is defined as an attempt to use monopoly power in one market to monopolize another market" and, thus, requires a "two-market situation"); *M.A.P. Oil Co. v. Texaco, Inc.*, 691 F.2d 1303, 1305 (9th Cir. 1982) (affirming dismissal of a monopoly leveraging claim where the evidence "would not justify a reasonable juror in concluding that distribution services exist as a distinct, separate and second market" from the "gasoline sales" market); *Grason Electric Co. v. Sacramento Municipal Utility Dist.*, 571 F. Supp. 1504, 1518 (E.D. Cal. 1983) ("there can be no unlawful leveraging unless the defendant is seeking a competitive advantage in the provision of goods or services that is analytically distinct from the supply of those goods and services over which the defendant has a lawful monopoly.").

In fact, an exhaustive search for cases in every circuit has confirmed that *every* circuit requires a distinct, separate second market to pursue a monopoly-leveraging theory. *See, e.g.*, *Surgical Care Ctr. of Hammond, L.C. v. Hosp. Serv. Dist. No. 1*, 309 F.3d 836, 839 (5th Cir. 2002) (monopoly leveraging claim involving a market for *inpatient hospital services* and a separate market for *outpatient surgical services*); *AD/SAT v. AP*, 181 F.3d 216, 230 (2d Cir. 1999) (monopoly leveraging claim involving a market for *new wire services* and a separate market for *advertising delivery services*); *Alaska Airlines, Inc. v. United Airlines, Inc.*, 948 F.2d 536, 548 (9th Cir. 1991) (monopoly leveraging claim involving *computerized reservations systems* and a separate market for *air transportation*).

By double-counting each ritonavir prescription – "once for the booster market and once for the boosted market" (Hurst Decl., Ex. J at 77:12-14, 79:19-25, 80:1-8) – Plaintiffs are relying on *overlapping* markets and, thus, have failed to meet the "threshold requirement" of defining a "second market, distinct from the first (monopoly) market." *Catlin*, 791 F.2d at 1346, 1349. By including Norvir prescriptions in *both* markets, Plaintiffs are treating the Boosted Market as *not* a "distinct,

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separate and second market" as required by the law of monopoly leveraging and, instead, as some sort of *overlapping* market, where the first market includes Norvir and a second market includes Norvir again in addition to boostable PIs.

Overlapping markets is doubly unreasonable because, as this Court has noted, the antitrust laws are implicated only when a patent owner "extends its monopoly *beyond the scope of the patent*." (10/21/04 Order at 4, Docket No. 63 (emphasis added)). Thus, sales in a *legitimate* patent monopoly certainly should not serve as evidence towards the creation of an *unlawful* monopoly. But that is exactly what Prof. Greer is proposing. He is counting sales of Norvir – which is indisputably patented – as evidence of an unlawful monopoly. Under his calculation method, Kaletra could have failed completely, literally losing all of its sales and been taken off the market, and Abbot would *still* have 50% of the Boosted Market based on Norvir sales indisputably protected by a patent.

Prof. Greer's duplicate counting also completely contradicts Plaintiffs' theory of the case. Plaintiffs are arguing that Abbott raised Norvir's price to *suppress* Norvir sales and, thus, *force* consumers to switch to Kaletra. Every sale of Norvir undermines that theory because that means a patient did *not* switch to Kaletra. But Prof. Greer is counting every Norvir sale to *support* his monopolization theory by counting those sales in the Boosted Market.

Because Plaintiffs' expert opinion is not "reasonable given the substantive law which is the foundation for the claim or defense," it does not raise a genuine issue of material fact. Thus, Abbott is entitled to summary judgment on this basis alone.[5]

[5] As the Court is aware, monopoly power alternatively can be demonstrated by direct evidence, which the Ninth Circuit has stated requires "evidence of restricted output and supracompetitive prices" – the hallmarks of a monopoly. *Rebel Oil*, 51 F.3d at 1434. In this litigation, Plaintiffs never have attempted to show either restricted output or supracompetitive prices in the Boosted Market. In its July 2006 Order, this Court stated that "[d]irect proof of market power may be shown by evidence of restricted output and supracompetitive prices. But it does not have to be shown by such evidence. It can also be shown by 'injury to competition which a competitor with market power may inflict, and thus, of the actual exercise of market power.'" (7/6/06 Order at 8, Docket No. 256 (quoting *Forsyth v. Humana, Inc.*, 114 F.3d 1467 (9th Cir. 1997)). Abbott respectfully submits that this statement was in error. The internal quote is an excerpt from *Forsyth*. But a critical portion of the relevant passage from *Forsyth* was omitted. The passage states in relevant part, that "[d]irect proof of market power may be shown by evidence of restricted output and supracompetitive prices. *Such a showing* is 'direct proof of the injury to competition which a competitor with market power may inflict, and thus, of the actual exercise of market power." 114 F.3d at 1475 (quoting *Rebel Oil*, 51 F.3d at 1434) (emphasis added). In other words, *Forsyth* merely

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IV. Abbott's Norvir Patents Immunize It From Antitrust Liability.

Abbott's patents also mandate summary judgment because, obviously, a patentee cannot be liable for "unlawfully" monopolizing a market that a patent gives it every legal right to monopolize. Basically, Plaintiffs argue that the Norvir price increase has made it more difficult for competitors to gain access to the Boosted Market. But, in fact, Abbott's patents give Abbott every right to exclude competitors *altogether* and, thus, exclusion from the Boosted Market cannot give rise to antitrust liability. (*See* 7/6/06 Order at 12, Docket No. 256 ("Legally, a patent amounts to a permissible monopoly over the protected work.")).

When earlier denying Abbott's patent-based arguments, the Court concluded that there are factual disputes concerning the scope of Abbott's '157 patent, whether the "'157 [patent] was anticipated and/or obvious," and whether Abbott "has impliedly licensed Norvir" for use as a booster. (7/6/2006 Order at 17, 19-20, 22, Docket No. 256). Since then, however, discovery has shown that: (1) the scope of Abbott's patents indisputably cover the Boosted Market; (2) Abbott's patents over the Boosted Market are not invalid; and (3) Abbott's grant of *express* licenses to competitors to recommend boosting their drugs with Norvir cannot render its patents unenforceable under the doctrine of *implied* license.

1. Abbott's Patents Cover Plaintiffs' Boosted Market.

When denying Abbott's patent immunity argument in its earlier summary judgment motion, the Court held that "Defendant must do more than name a few of its patents, quote a couple of lines from each patent, and assert that each patent clearly covers the boosted market." (07/06/06 Order at 16, Docket No. 256). Abbott has taken the Court's concerns to heart and, thus, fully establishes below that its patents cover the so-called Boosted Market.

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held – like *Rebel Oil* – that evidence of restricted output and supracompetitive prices is direct proof of market power, not that there are other types of evidence that may also qualify as direct proof of market power. Indeed, *Forsyth* rejected the proffered "direct evidence" because the evidence of "higher prices" was insufficient without an "accompanying showing of restricted output." *Id*. at 1476; *accord Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007) ("The existence of monopoly power may be proven through direct evidence of supracompetitive prices and restricted output."); *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (en banc) (same); *Coastal Fuels of Puerto Rico, Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196-97 (1st Cir. 1996) (same).

Claim construction "is an issue of law" for the Court and, thus, is appropriately resolved on summary judgment. *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1347 (Fed. Cir. 2007). The analysis "begin[s] with the language of the claims." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005)), and there is a "heavy presumption that [claim terms] carry their ordinary and customary meaning to those skilled in the art in light of the claim term's usage in the patent specification." *Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 2007-1097, 2007 U.S. App. LEXIS 27399, *10 (Fed. Cir. Nov. 28, 2007).

Here, there is no dispute about the claim terms' ordinary meaning. To simplify this summary judgment motion, Abbott is relying on only two patent claims out of the dozens of applicable claims: claim 22 from U.S. Patent No. 6,703,403 and claim 9 from U.S. Patent No. 6,037,157. Dependent claim 22 of the '403 patent, written in its independent form, specifically covers Norvir's boosting of "an HIV protease inhibitor":

> A method for improving the pharmacokinetics of an HIV protease inhibitor comprising administering to a human in need of such treatment an amount effective to inhibit cytochrome P450 monooxygenase of ritonavir or a pharmaceutically acceptable salt thereof.

(Hurst Decl., Ex. K at 12:28-36). Claim 9 from the '157 patent similarly covers:

> A method for increasing human blood levels of a drug which is metabolized by cytochrome P450 monooxygenase comprising administering to a human in need of such treatment a therapeutically effective amount of a combination of said drug or a pharmaceutically acceptable salt thereof and ritonavir or a pharmaceutically acceptable salt thereof.

(Hurst Decl., Ex. M at 14:15-21).

The plain language of these claims covers the Boosted Market. Claim 22 of the '403 patent is expressly directed to boosting an "HIV protease inhibitor." Claim 9 of the '157 patent is directed to boosting "a drug which is metabolized by cytochrome P450 monooxygenase," while the

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specification explicitly states that "an HIV protease inhibitor" is one of the drugs "metabolized by cytochrome P450 monooxygenase." (Hurst Decl., Ex. M at 1:66-67; 11:49-53). As Abbott's technical expert explains, "all of the PIs in the Boosted Market are metabolized by cytochrome P450 monooxygenase." (Hurst Decl., Ex. O at ¶ 29). Thus, both the '157 patent and the '403 patent cover the so-called "Booster Market." (*Id*. at ¶¶ 22, 40).

The claims' plain language is consistent with the invention described in the patents' specification. The patents' specification notes that the prior art disclosed only one use for Norvir – that is, to inhibit HIV's protease enzyme, which is important to HIV replication. (Hurst Decl., Ex. M at 1:46-48; Hurst Decl., Ex. K at 1:50-52). Nothing in the prior art disclosed Norvir's ability to inhibit cytochrome P450, which is an enzyme that naturally occurs in the human body and essentially tears apart most PI's. (Hurst Decl., Ex. X at ¶ 102). The specification of the '403 and '157 patents therefore describe an entirely new use of Norvir – that is, inhibiting cytochrome P450 to "boost" the blood levels of companion PIs and, thus, allow them to work with substantially lower doses and reduced side effects. (Hurst Decl., Ex. M at 1:49-2:2; Hurst Decl., Ex. K at 1:53-2:5). That new use is expressly recited in the asserted claims – i.e., "a method of increasing human blood levels of a drug which is metabolized by cytochrome P450" and "a method for improving the pharmacokinetics of an HIV protease inhibitor." (Hurst Decl., Ex. M at claim 9; Hurst Decl., Ex. K at claim 40).

To further confirm that Abbott's claims cover the Boosted Market, Dr. Fletcher, a world-renowned HIV clinician and pharmacokineticist, comprehensively and thoroughly reviewed the plain meaning of the claims of Abbott's two booster patents, '157 and '403 patents, as well as U.S. Patent No. 5,886,036. (Hurst Decl., Ex. O at ¶ 20-50). He concludes, "It is my professional and expert opinion that multiple claims of Abbott's patent Nos. 6,703,403, 6,037,157 and 5,886,036 fully cover Plaintiffs' Boosted Market." (*Id*. at ¶ 16; *accord id.* at ¶¶ 20-50).

Plaintiffs' technical expert, Dr. Volberding, agreed. He testified, for instance, that, based on the '403 patent's plain language, Abbott's patent claims cover "what's happening in the marketplace today" with respect to Norvir's use as a booster. (Hurst Decl., Ex. N at 60:24-61:4, 62:10-19).

As additional support for its claim constructions – and because of the potential need for a

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Markman ruling on other relevant claims that also cover Plaintiffs' Boosted Market – Abbott has attached a detailed claim chart outlining: (1) each claim Dr. Fletcher has identified as covering the Boosted Market based on the plain language as understood by those of skill in the art; (2) the meaning of the relevant claim terms; and (3) the legal and factual support for its interpretation. (Hurst Decl., Ex. T). Before filing this summary judgment motion, Abbott asked Plaintiffs for the basis of their conclusion that Abbott's asserted claims do not cover the Boosted Market, but Plaintiffs declined to provide Abbott with any competing claim constructions. To the extent that Plaintiffs dispute the meaning of any claim term, Abbott will address those new arguments in its reply brief.

2. Abbott Did Not Disclaim The Use Of Norvir As A PI-Booster.

In an earlier opinion, before rendering any *Markman* decision, the Court noted a dispute over whether Abbott's '157 patent prosecution history "disclaimed" the use of Norvir as a booster for other protease inhibitors and, thus, whether the '157 patent in fact covers the "Booster Market." (07/06/06 Order at 16, Docket No. 256). As the Federal Circuit recently emphasized, however, "the prosecution history represents an ongoing negotiation between the PTO and the applicant" and, thus, "often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 2007 U.S. App. LEXIS 27399, *13-14 (Fed. Cir. Nov. 27, 2007). Accordingly, for "a prosecution statement to prevail over the plain language of the claim, the statement must be clear and unmistakable." *Id.* at *15.

Plaintiffs thus bear the heavy burden of showing a "clear and unmistakable" disclaimer. They cannot meet that burden. Plaintiffs have argued that Abbott *implicitly* disclaimed the use of Norvir to boost PIs – which is the main point of both the '157 and '403 patents – by failing to deny the Patent Examiner's statement that "it would have been obvious to one skilled in the art to combine Ritonavir with other HIV protease inhibitors for treating an HIV infection." (Hurst Decl., Ex. S; Plaintiffs' 2/10/06 Op. Mem. at 19, Docket No. 211). But, of course, combining PIs together to inhibit HIV's protease enzyme is not the claimed invention and, thus, there was no reason to deny that statement.

As further detailed in the next section, when a patent's claims are directed to a method of

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treatment for a "human in need thereof," the claims cover treating the human with "*the intent to achieve the objective stated in the preamble*." *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1330 (Fed. Cir. 2003) (emphasis added). Thus, it is irrelevant that the prior art discussed using Norvir as a *protease inhibitor* in a cocktail with other HIV drugs, including PIs. As Abbott argued specifically to the PTO during prosecution, the prior art did not teach the claimed boosted invention – namely, the different "use of ritonavir to improve the pharmacokinetics of a drug which is metabolized by cytochrome P450 monooxygenase." (Hurst Decl., Ex. S at NOR 114392). The examiner agreed, finding that "the applicants arguments (paper no. 13) were persuasive regarding failure of [the prior art] to teach improving the pharmacokinetics of a drug . . . with ritonavir." *Id*. at NOR 114395.

Dr. Volberding agreed, too. After reading "with care" the relevant prior art patent – the '882 patent (Kempf), he acknowledged that it did not disclose Abbott's claimed boosting invention:

> Q. [A]nd now I'll focus on the third subsection [of the relevant Abbott argument from the prosecution history], is it also true that Kempf does not teach or suggest – and I'm quoting now – "the use of ritonavir to increase the blood levels of a drug which is metabolized by cytochrome P450 monooxygenase"?
>
> A. I'm less certain here, as the patent, as I read it, does include the use of ritonavir in combination with other proteases which its action would inhibit cytochrome P450.
>
> Q. But my question is whether the patent itself teaches the use of ritonavir to increase the blood levels of a drug which is metabolized by cytochrome chrome P450 monooxygenase.
>
> A. In my read, it didn't specifically address that.

(Hurst Decl., Ex. N at 240:12, 241:1-10).

In response to Abbott's earlier summary judgment motion, which focused on the '157 patent, Plaintiffs also argued that Abbott "disclaimed" coverage over the "Boosted Market" by canceling certain PI-specific claims. This argument ignored the fact that Abbott specifically included those claims in a related divisional patent application. (Hurst Decl., Ex. K at "Related U.S. Application Data"; 7/6/06 Order at 15, Docket No. 256). And in any event, Abbott is now asserting the '403 patent, which is the very patent that resulted from that divisional application and which specifically

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incorporates those supposedly abandoned claims. (Hurst Decl., Ex. K at "Related U.S. Application Data" (explaining connection between applications)). So instead of *cancelling* PI-specific claims, Abbott specifically *added* PI-specific claims to the '403 patent. (Hurst Decl., Ex. K at claims 4, 22, 40, 49, 67, 85). Thus, those claims are hardly "disclaimed."

The fact that Abbott's patents cover the "Boosted Market" is doubly confirmed by the fact that the specifications of both the '403 patent and the '157 patent repeatedly refer to ritonavir's use to boost "protease inhibitors." (Hurst Decl., Ex. K at 1:55-56, 2:1, 2:5, 2:27, 2:37, 2:43, 2:54, 8:16-17, 8:20, 9:34, 9:36, 9:39-40; Ex. M at 1:51-52, 1:66, 2:2, 2:25, 2:37, 2:42, 2:54-55, 10:31-32, 10:35, 11:50, 11:52, 11:54; Ex. T). That is the heart of the claimed invention. And the only person of ordinary skill in the art to opine on the subject, Dr. Fletcher, concluded after reviewing the claims, specification, and prosecution history that the '157 and '403 patents specifically cover the boosting of PIs. (Hurst Decl., Ex. O at ¶¶ 21-22, 39-40). Thus, it is undisputed that "reading the specification and remainder of the intrinsic record as a whole would lead those skilled in the art to the conclusion that [Abbott's] statement . . . was not a clear and unmistakable surrender of claim scope." *Elbex Video*, 2007 U.S. App. LEXIS 27399 at *14-15.

Absent any purported "clear and unmistakable disclaimer," the undisputed plain language of the relevant claims controls. And under that plain language, Abbott has patents that cover the "Boosted Market," which means Abbott cannot be charged with "unlawfully" monopolizing that market.

3. Plaintiffs' Validity Argument Is Defective As A Matter Of Law.

Plaintiffs next argue that Abbott is not entitled to the protections of its patents because the '157 and '403 patents are supposedly invalid based on the doctrine of "inherent anticipation" – that is, that Abbott's invention was not "new" on the relevant date in July 1995 because a prior art reference allegedly "inherently" disclosed the invention already.

To show anticipation, Plaintiffs must show that "the four corners of a single, prior art document describe[d] every element of the claimed invention, either expressly or inherently." *Advanced Display Sys. Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) (citations omitted). For an element to be inherently disclosed, "the practice of [the prior art reference] always

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yields" every limitation of the claimed invention. *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047-48 (Fed. Cir. 1995). The "extrinsic evidence must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (emphasis added). Inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.*

This Court previously held that validity arguments are relevant to the antitrust analysis because "Plaintiffs seek to address future harm" and, thus, a future invalidity finding presumably could trigger the right to an injunction based on "future monopolistic conduct." (07/06/06 Order at 22, Docket No. 256). Though Abbott respectfully disagrees with that ruling, Plaintiffs' invalidity theory nevertheless fails as a matter of law. Plaintiffs argue only that the '157 and the '403 patents are "inherently anticipated" based on the alleged "inherent" boosting that would occur if anyone followed the prior art '882 patent's suggestion to include Norvir in an HIV-drug cocktail along with other PIs. That argument fails because, first, the '882 patent discloses using Norvir *only* as a PI, not as a booster as claimed in Abbott's patents and, second, the '882 patent fails to discuss administering Norvir to any human who "needed" a boost, as also claimed in Abbott's patents.

Plaintiffs' anticipation argument simply ignores the language of the relevant claims. Abbott's booster patents contemplate more than just administering Norvir as part of a drug cocktail that includes other PIs. The patents are directed toward using Norvir for a *specific purpose*, namely to boost the blood levels of another PI for patients "in need of" such a boost. Claim 22 of the '403 patent is directed to a "method for improving the pharmacokinetics of an HIV protease inhibitor" by administering Norvir "to a human in need of such treatment." (Hurst Decl., Ex. K at 12:28-36). Claim 9 of the '157 patent is phrased in the same way. It is directed to a "method for increasing human blood levels of a drug" by administering Norvir to "a human in need of such treatment." (Hurst Decl., Ex. M at 14:15-21).

Under settled law, when a claim's stated purpose is to treat "a human in need thereof" or to administer a drug "to a human in need of such treatment," that stated purpose becomes an element of the claim. For example, in *Jansen v. Rexall*, the Federal Circuit addressed a claim directed to

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methods of "treating or preventing macrocytic-megaloblastic anemia" by administering a drug combination "to a human in need thereof." *Jansen*, 342 F.3d at 1330. As the Federal Circuit explained, because the claim language "requires that the method be performed on 'a human in need thereof,'" the claim requires "that the method be practiced with *the intent to achieve the objective stated in the preamble*." *Id.* at 1333 (emphasis added).

Thus, an intent to "boost" is an explicit element of Abbott's patents' claims. This means that anticipation can occur only if the prior art discloses a treatment method carried out with that specific objective. *See, e.g., Glaxo Group Ltd. v. Teva Pharms. United States*, No. 02-219, 2004 U.S. Dist. LEXIS 16750, *57 (D. Del. Aug. 20, 2004) (rejecting inherent anticipation argument where the prior art composition and method were "not directed at the same purpose as administration of the drug to patients in need of nausea and emesis relief"); *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, IP 02-0512, 2004 U.S. Dist. LEXIS 14724, *86-87 (S.D. Ind. 2004) (rejecting an inherent anticipation argument, because the challenger did not prove that "the alleged prior art references require an intent to treat PMS"); *see also* 13 Fed. Cir. B.J. 562 (explaining that according to *Jansen*, "infringement of a method of treatment/prevention claim requires that an alleged infringer have an intent to treat or prevent the specific disease/disorder recited in the preamble if the body of the claims limits the method to one in need thereof"); Richard A. Castellano, *Note: Patent Law For New Medical Uses Of Known Compounds And Pfizer's Viagra Patent*, 46 IDEA 283, 296 (2006) ("*Jansen v. Rexall Sundown Inc.* provides a safe harbor from the broadly construed anticipation doctrine for pharmaceutical and biotechnological inventions. . . . Under *Jansen*, the preamble is 'not merely a statement of effect that may or may not be desired . . . but a statement of [] intentional purpose for which the method must be performed.'").

Plaintiffs do not even allege that the prior art '882 patent discloses using Norvir with the *claimed purpose* of boosting another PI. Instead, that patent indisputably discusses using Norvir for a *different purpose* – namely, using the drug to inhibit the protease enzyme as part of a larger HIV-drug cocktail that includes another protease inhibitor. (E.g., Hurst Decl., Ex. K at 2:1-5; Hurst Decl., Ex. M at 1:65-2:2). Plaintiffs' expert, Dr. Volberding, admits this point. He concedes that "nothing in the scientific literature and nothing in the prior art discloses any instance *even hinting* that" Norvir

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could be used "with the express intent" of providing a pharmacokinetic "boost." (Hurst Decl., Ex. N at 45:5-13). Thus, Plaintiffs' anticipation argument fails as a matter of law.

Plaintiffs' argument fails for another independent reason. Both of the asserted claims contemplate administrating Norvir to a patient "in need of" a boost. But, generally, the only patients who "need" a boost are those who are taking a *reduced* dose of the companion PI – a concept not disclosed anywhere in the prior art. (Hurst Decl., Ex. X at ¶¶ 118-126). In fact, when Abbott first discovered that Norvir could boost other PIs, it immediately alerted the public that combining Norvir and saquinavir could "be very dangerous unless the dose of saquinavir is drastically reduced." (Hurst Decl., Ex. W). Thus, patients taking full doses of saquinavir – which is all the prior art disclosed – certainly did not "need" a boost from Norvir. (*See* Hurst Decl., Ex. N at 69:7-17).

Dr. Volberding admits this point, too. Far from the "in need of" claim element "always" and "necessarily" being present, as required to prove inherency, he concedes that administering Norvir in accordance with the '882 patent would *not* "necessarily" constitute administration to a patient "in need of" a boost. (*Id*. at 66:17-67:16). He explained that "if you're saying do all patients need that benefit, I'd say, no, they don't all need it." (*Id*. at 68-3-5). He further conceded:

> Q. In the art that you cited, in the prior art, can you think of an instance where it was necessarily true that all patients taking the combinations you've identified would actually need the inhibition of cytochrome P450 monooxygenase?
>
> A. I think, as I've said, while I don't think all patients would need the use of ritonavir, I think some patients would benefit from the use of ritonavir in that situation.
>
> Q. That's because – let me understand your opinion because this is awfully helpful, and that's because it really depends on the blood levels being achieved with the full dose of the original PI; correct?
>
> A. Well, certainly ritonavir use can change the blood levels of the other PI and in some cases that would be a benefit to the patient.
>
> Q. But not in all cases?
>
> A. Not in all cases.

(*Id*. at 66:17-67:16).

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As a matter of law, therefore, Plaintiffs' anticipation argument fails. The prior art '882 patent simply does not disclose, expressly or inherently, either the claimed method of treatment (using Norvir specifically for the purpose of boosting) or using that method with the claimed patients (those who "need" a Norvir boost). Thus, Abbott's valid patents preclude liability for allegedly "monopolizing" the Booster Market.[6]

4. Plaintiffs Cannot Strip Abbott's Patent Rights Through The Doctrine Of Implied License.

Plaintiffs next contend that Abbott's patents do not give it "the power to exclude competitors . . . because Defendants impliedly licenses patients to use Norvir as a booster." (7/6/06 Order at 18, Docket No. 256). As this Court explained, Plaintiffs reason that Abbott "cannot sell Norvir for boosting use," thus impliedly license patients, and then turn around "exclude competitors from the boosted market." (*Id*. at 17). When previously finding a factual issue over whether Abbott had waived its right to exclude, this Court noted that Abbott's express licenses were "not in the record." (*Id*. at 19).

Abbott has now submitted all of its license agreements in the Boosted market. (*See* Hurst Decl., Exs. A, B, C, E, F). These license agreements demonstrate that Abbott has enforced – not waived – its patent rights, including the right to exclude new and old competitors to whatever extent it chooses consistent with those license agreements. Abbott has licensed 89% of competitive sales in the Boosted Market through licenses with *all* of its top PI competitors, including BMS, GSK, BI and Tibotec – none of whom would be paying a royalty if Abbott had no right to exclude them. (Hurst Decl., Exs. A, B, C, E, F). These license agreements expressly contemplate that – without fear of

[6] It is not clear whether Plaintiffs are attempting to maintain an obviousness defense for the asserted claims of the '403 and '157 patents. They have provided no expert opinion on any such defense, which plainly is inapplicable. Where a defendant asserts that a patent is obvious, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007) (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007)). Here, Dr. Volberding – Plaintiffs' only scientific expert – confirmed that he is "offering no opinion in this proceeding regarding whether any of the asserted claims in the '403 patent are obvious or not." (Hurst Decl., Ex. N at 42:15-19). On the contrary, he "agree[d] that before June 29, 1995, nothing in the scientific literature and nothing in the prior art discloses any instance even hinting that ritonavir was to be given with the express intent of improving the pharmacokinetics of a companion PI." (*Id*. at 45:5-12). This alone defeats any purported obviousness defense.

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any lawsuit and in exchange for a royalty – Abbott's competitors could "recommend, label, market, use, sell, have sold and offer to sell one or more of the GSK Products . . . in co-prescription and/or coadministration with Ritonavir in any strength." (Hurst Decl., Ex. F at ¶ 2.1; *accord* Hurst Decl., Ex. A at 1, B at 1, C at 1, E at 1).

A license agreement, of course, is not an *abandonment* of a patent and its accompanying right to exclude. It is the opposite – it is the *enforcement* of the right to exclude by charging a toll for market entry and, thus, *preserves* patent rights. In exchange for a royalty payment, the license merely represents a "covenant by the patent owner not to sue the licensee for making, using, or selling the patented invention." *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1345 (Fed. Cir. 2001); *accord Spindelfabrik Suessen-Schurr Stahlecker & Grill GmbH v. Schubert & Salzer Maschinenfabrik Aktiengesellschaft*, 829 F.2d 1075, 1081 (Fed. Cir. 1987) (explaining that a license agreement "is in essence nothing more than a promise by the licensor not to sue the licensee").

To the extent that Abbott has "excluded" any of its licensed competitors from the purported "Boosted Market," those competitors may have a *contract action* to the extent that the license agreements specifically preclude Abbott's allegedly exclusionary conduct. But the competitors certainly could not bring an *antitrust action*, particularly not after effectively agreeing through the license agreement that Abbott had a patent over the purported "Boosted Market." After all, "a patent amounts to a permissible monopoly over the protected work." (*See* 7/6/06 Order at 12, Docket No. 256); *see also Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 422 (U.S. 1908) (A patent owner is "one who has discovered something of value. It is his absolute property. He may withhold knowledge of it from the public, and he may insist upon all the advantages and benefits which the [Patent Act] promises.").

Despite Abbott's active enforcement of its patent rights, Plaintiffs argue that Abbott has "waived" its right to exclude competitors by selling Norvir to *patients* without restriction and, thus, impliedly licensing patients to use Norvir as a booster. If that were true, of course, none of Abbott's competitors would be paying a royalty to avoid exclusion from the marketplace. In any event, as Abbott previously noted, the "patients who buy PIs . . . have the benefit of its express license

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agreements." (7/6/06 Order at 19, Docket No. 256). Thus, patients using Norvir to boost other PIs is the result of Abbott's active *enforcement* of its patent rights (*i.e.*, its licensing program) rather than Abbott's *waiver* of those rights (*i.e.*, allowing patients to use Norvir as a booster without suing them).

The Court previously noted Plaintiffs' argument that the agreements "do not expressly authorize patients to use Norvir as a booster." (*Id*. at 19). But that argument is irrelevant. The Federal Circuit has ruled that end users are the direct beneficiaries of an express license agreement under these circumstances *regardless* of whether they are expressly referenced. *Jacobs v. Nintendo*, 370 F.3d 1097, 1101 (Fed. Cir. 2004). In *Jacobs*, the court held that a license agreement granting a right to sell a product for an infringing use "barred [the patentee] from interfering with that right by prohibiting [the licensee's] customers from using" the product in an infringing way. *Id*. The court reasoned that "basic contract law principle that a party may not assign a right, receive consideration for it, and then take steps that would render the right commercially worthless." *Id*. Thus, the customers were effectively "implied sub-licensees" of the express licensee agreement.

Jacobs controls here. Abbott had no right to sue patients who used Norvir to boost the PIs of licensed competitors and, thus, cannot "waive" its patent rights by failing to do so. The whole point of Abbott's license agreements was to *allow* – in exchange for a payment – Abbott's competitors to promote their products' use in combination with Norvir. Those contracts thus barred Abbott from turning around and suing all the patients who followed that licensed recommendation. Nor would it have been practical to do so. *See* Mark A. Lemley, *Inducing Patent Infringement*, 39 UC DAVIS LAW REVIEW 225, 228 (2005) (noting that it is "impractical" to sue every doctor and individual patient). Thus, short of withholding its invention altogether outside the use of Kaletra, Abbott has done everything reasonably possible to enforce its patents, which means Abbott has not "waived" its core right to exclude competitors to whatever extent it wishes consistent with its license agreements.

Moreover, whether or not Abbott "impliedly licensed" *patients* is irrelevant to an antitrust analysis. The "purpose of the antitrust laws is to promote *competition*" (*7-UP Bottling Co. v. Archer Daniels Midland Co. (In re Citric Acid Litig.)*, 191 F.3d 1090, 1094 (9th Cir. 1999)) and, thus, the question is whether Abbott has abandoned its right to exclude *competitors*. Abbott obviously has not

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done so given its active licensing program. Thus, it plainly retains the right to enjoin any new competitor and any licensed competitor who ceases to make royalty payments.

Finally, regardless of whether Abbott provided *patients* with an implied license, that fact would in no way undermine Abbott's right to set monopoly prices for its patented inventions, including the use of Norvir as a booster. Any such implied license would be created only when a patient *purchases* Norvir at the price Abbott sets. "An implied license arising from sale of a component to be used in a patented combination extends only for the life of the component whose sale and purchase created the license." *Anton/Bauer, Inc. v. PAG, Ltd.*, 329 F.3d 1343, 1352 (Fed. Cir. 2003). Thus, to obtain each new "implied license," patients must accept the terms that Abbott sets for purchasing Norvir, namely the new price. They do not have an "implied license" otherwise and, thus, Abbott's pricing decisions still could not qualify as an antitrust violation.

In the end, Plaintiffs cannot avoid Abbott's right to exclude competitors based on arguments about an implied license to patients. Because Abbott plainly has a right to exclusivity over the Boosted Market based on its valid booster patents, Abbott cannot be liable under the Sherman Act for allegedly "monopolizing" that market.

V. Plaintiffs' State Law Claims Fail As A Matter Of Law.

Plaintiffs' state law claims fail for three independent reasons.

1. Plaintiffs' Inability To Sustain Their Sherman Act Claim Requires Summary Judgment On Their State Law Claims.

As this Court has noted, the "parties agree that if the anti-trust claims fail, both of the Plaintiffs' State law claims fail as well." (7/06/06 Order at 23, Docket No. 256). Because Abbott is entitled to summary judgment on Plaintiffs' Sherman Act claim for the many reasons set forth above, this Court also should grant Abbott summary judgment on Plaintiffs' claims for unjust enrichment and alleged violations of California's Unfair Competition Law.

2. Abbott's Undisputed Good Faith Belief That Its Norvir Patents Are Valid Precludes Plaintiffs From Recovering Damages In This Case.

Regardless of the outcome of the patent validity issue, Abbott's patents defeat Plaintiffs' state law claims, under which Plaintiffs are seeking damages for past conduct.

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When permitting discovery on the validity issues, this Court noted that Plaintiffs "are not seeking retroactive damages for past anticompetitive conduct" and, instead, "seek to address *future* harm" and "*future* monopolistic conduct" through an injunction. (07/06/06 Order at 22, Docket No. 256). Thus, even if they could prove that the asserted patents are invalid (which they cannot), Plaintiffs would at most be entitled to *injunctive* relief for *future* harm to competition – i.e., conduct that post-dated a possible finding of invalidity someday in the future.

As this Court previously has recognized, "a patentee who has a good faith belief in the validity of a patent will not be exposed to antitrust damages even if the patent proves to be invalid." (7/6/06 Order at 22 (quoting *CVD, Inc. v. Raytheon Co.*, 769 F.2d 842, 850 (1st Cir. 1985)). Instead, a patent owner can be liable for patent damages for anticompetitive conduct only when acting in bad faith either by filing lawsuits over the patent while knowing it is invalid (sham litigation) or by procuring the patent from the patent office through fraud (*Walker-Process* fraud). *See Bourns, Inc. v. Raychem Corp.*, 331 F.3d 704, 711 (9th Cir. 2003) (*Walker-Process* fraud); *Amarel v. Connell*, 102 F.3d 1494, 1517-18 (9th Cir. 1996) (sham litigation).

Plaintiffs never have contended – nor could they – that Abbott lacked a good-faith belief that its booster patents are valid. Thus, Abbott's patents preclude monetary damages resulting from Abbott's past actions – both in a federal antitrust context and from Plaintiffs' state-law claims resulting from that alleged antitrust violation.

3. *Illinois Brick* Precludes Plaintiffs From Recovering Damages On Their State Law Claims.

Finally, Plaintiffs' unjust enrichment claim cannot circumvent the indirect purchaser rule in *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977). As other federal courts have held, *Illinois Brick*'s clear bar on indirect purchaser recovery also prohibits recovery under a tag-along common law claim for unjust enrichment. *See e.g.*, *In Re New Motor Vehicles Canadian Export Antitrust Litig.*, 350 F. Supp. 2d 160, 207 (D. Me. 2004). In *In re New Motor Vehicles*, the court explained:

> Certainly no restitutionary remedy can escape the limitations the United States Supreme Court imposed on federal antitrust recovery in *Illinois Brick*, and the plaintiffs do not argue that it can. Therefore, as

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> indirect purchasers, the plaintiffs may not use state common law restitution to recover money from the defendants for violation of the federal antitrust laws.

Id. at 210-11. The only allegation of wrongdoing here is a violation of the federal antitrust laws. Accordingly, Plaintiffs' state law claims cannot escape the rule of *Illinois Brick*, and Plaintiffs should not be allowed to recover money damages on those claims. *Id.*; *In re Terazosin*, 160 F. Supp. 2d 1365, 1379-80 (S.D. Fla. 2001) (dismissing unjust enrichment claims predicated solely on federal antitrust violations).

CONCLUSION

For the foregoing reasons, Abbott respectfully requests that its motion for summary judgment be granted.

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RESPECTFULLY SUBMITTED,
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